

Remarks

Status of Claims:

Claims 1, 4, 8-20 stand rejected. Claims 21, 22 and 23 are added.

Claims 1, 4, 8-20 and 21-23 remain pending.

The amendments are supported by the application and drawings as filed. No new matter is added.

102 Rejections:

Kumar (US7236816)

Claim 1 is rejected as anticipated by Kumar. The Examiner is respectfully urged to reconsider the rejection in view of the following.

It is respectfully urged that the Examiner has interpreted Kumar as teaching more than Kumar actually teaches, and that Claim 1 includes multiple elements not disclosed in Kumar.

Claim 1 recites, among other things, a distal needle segment formed of a non-metallic first material having a lateral tissue receiving port disposed distally of the proximal end of the needle, a tissue piercing tip associated with the distal end of the distal needle segment; and a proximal needle segment formed at least in part of a metallic second material, the proximal needle segment disposed proximally of the tissue receiving port.

Claim 1 also recites the proximal needle segment and the distal needle segment provide at least one substantially continuous lumen, wherein the proximal needle segment and the distal needle segment are longitudinally joined along a common axis; and that a portion of the proximal needle segment extends distally of the proximal end of the distal needle segment.

The Examiner applies Kumar by stating that Kumar teaches a needle 1610 having a proximal needle segment and a distal needle segment (though it is not clear what portion of needle 1610 the Examiner considers to be the proximal portion and the distal portion). The Examiner also applies Kumar as having a slide slot 1612 and, according to the Examiner, a hollow core.

The Examiner then goes on to say that Kumar

“suggests the distal needle segment may include *segments* formed of a non-magnetic non-metallic material (col 23, lines 45-67 ; col 24, lines 1-11). Italics added.

A review of column 23, lines 45-67 and column 24, lines 1-11 of Kumar does not appear to support or suggest that the biopsy needle 1610 of Kumar includes segments. Column 23, lines 53-54 explain that

“The biopsy needle 1610 and *associated circuits 1650* can be fabricated from non-magnetic materials.” Italics added.

It is respectfully urged that the associated circuits 1650 are electrical circuits, and not needle segments.

Kumar goes on to say at column 23, lines 57 that the biopsy needle 1610 may have a hollow core near its distal end 1619, but the Kumar does not teach or suggest that biopsy needle 1610 should include either:

1. proximal needle segment and the distal needle segment; or
2. proximal and distal needle segments that provide a substantially continuous lumen; or
3. proximal needle segment and the distal needle segment are longitudinally joined along a common axis; and that a portion of the proximal needle segment extends distally of the proximal end of the distal needle segment.

Kumar at column 24, lines 1-11 explains that an insulator 1618 may extend as far as the ends of a cannula 1613, to insulate an obturator in the cannula 1613. Column 24, lines 5-11 describe various

materials from which the insulation layer may be formed, and that cannula 1613 may be covered with an insulating layer.

It is respectfully urged that Kumar does not suggest, (little less provide an anticipatory teaching of) a needle having proximal and distal segments formed of different materials, or proximal and distal needle segments that provide a substantially continuous lumen. It is respectfully urged that at most Kumar teaches the needle 1610 may have a hollow core near its distal end. Nothing in Kumar teaches needle 1610 has a continuous lumen extending through both a proximal needle portion and a distal needle portion.

Next, the Examiner states:

“The proximal needle segment (1710) of the Kumar device is coupled to the distal needle segment and is formed at least in part of metal. The two coupled segments create a continuous lumen between the distal and proximal portions of the device (Figure 17).”

Kumar does not teach that element 1710 of Kumar is “proximal needle segment” as the Examiner implies. Instead Kumar teaches that Figure 17 “illustrates electrical connections of the antenna shown in Figure 16.” Accordingly, it is respectfully urged that the electrical connections described by Kumar in connection with Figure 17 do not provide any teaching or suggestion that biopsy needle 1610 of Kumar includes multiple segments.

In addition, it is not seen where “segment (1710)” to which the Examiner refers is located in the Figure 17. It is not in the portion of the Figure 17 the Examiner includes on page 3 of the final rejection of August 18, 2009, and it does not seem to be in Figure 17 of Kumar. The Examiner should explain this or withdraw the rejection.

Claim 19/ Miller (US 6758824)

Claim 19 is rejected as anticipated by Miller (US 6758824). This rejection should be withdrawn for at least the following reasons.

The Examiner states that Miller teaches a

“distal needle segment (50) having a lateral tissue receiving port (55) and is distal from the target site when the device is in operation.”

The Examiner goes on to say that Miller has a “proximal needle segment (15)”...

This is not a correct reading of Miller.

First, as explained in previous responses, the Examiner has reversed the ordinary and customary meaning of “proximal” and “distal.”

Second, even if the Examiner is assumed (for the sake of argument only) to be using the words proximal and distal correctly, the rejection is still not correct, based on Miller’s own teachings.

Miller teaches element 15 is “outer cannula 15”. In addition, Miller teaches at column 6, lines 20-22:

“The cutting element 11 further includes an inner cannula 17 that fits concentrically within the outer lumen 27 (Fig 5) of the outer cannula 15. “

Further, by Miller’s own teaching element 50 is not a “distal needle segment” (or any needle segment), and element 55 is not a “lateral tissue receiving port”

Instead, Miller teaches at column 8, line 10:

“The aspiration tube 50 communicates with a collection trap 55...”

Figure 2 of Miller shows tube 50 spaced from the closest end of cannula 15 (the proximal end of cannula 15). It is respectfully urged that if cannula 15 is considered the biopsy needle or a segment of the biopsy needle, tube 50 cannot properly be considered a segment of the same needle where tube 50 is shown as being physically spaced from cannula 15.

Accordingly, it is respectfully urged that an aspiration tube 50 is not properly considered a segment of a needle as recited in column 19, nor a “distal needle segment”.

Note Miller also teaches at column 8, lines 16-22:

“This vacuum then draws a tissue sample excised at the working end of the cutting element 11, all the way through the inner cannula 17, tubular axle 43 and aspiration tube 50 until it is deposited in with the trap.” Underlining added.

Miller clearly teaches the tissue sample goes through inner cannula 17 on their way to tube 50. So, tube 50 is not properly considered being a segment of needle that includes cannula 15. Instead, tube 50 by Miller’s own teaching provides a path for tissue samples, along with axle 43 and cannula 17, not with cannula 15.

See Figure 5 of Miller which shows the relationship of inner cannula 17, and outer cannula 15, which the Examiner states is a “proximal needle segment (15)”. It is clear that if a tissue sample goes “all the way through cannula 17” in route to tube 50” as Miller teaches, then Miller does not teach or suggest that tube 50 is part of or otherwise a segment of the cannula 15 in Miller.

In addition, Applicants’ Claim 19 recites, among other things, the distal needle has a lateral tissue receiving port communicating with a distal cutter lumen segment; and that the proximal needle segment provides a proximal cutter lumen segment communicating with the distal cutter lumen segment.

It is clear from Miller’s own teachings that:

1. tube 50 of Miller does not include a cutter lumen, as recited in Claim 19;
2. Tube 50 does not have a distal cutter lumen segment communicating with a proximal cutter lumen.

Third, it is respectfully urged that even if one, contrary to Miller's own teachings, assumed that tube 50 is a distal needle segment with a distal cutter lumen segment, Miller would still not teach or suggest the following subject matter of Claim 19:

the distal end of the proximal needle segment is positioned distally of the proximal end of the distal needle segment.

*It is respectfully urged that the Examiner has not even addressed this portion of Claim 19, and the rejection should be withdrawn.*

Obviousness Rejections:

Claims 8 and 10-14

Claims 8 and 10-14 are rejected as obvious over Kumar in view of Frederick (US 6017356). This rejection is improper for all the reasons set forth above with respect to Kumar.

In addition, the rejection is improper for at least the following additional reasons.

Claim 13 recites, among other things, the proximal needle segment and the distal needle segment provide a continuous vacuum lumen.

The Examiner seems to agree that Kumar does not disclose a vacuum lumen as recited, but states that Frederick discloses a vacuum lumen.

Frederick discloses a trocar, not a biopsy needle. It is respectfully urged there is no motivation to place a vacuum port from a trocar on the biopsy needle of Kumar.

Further, even if one literally combined the vacuum port of Frederick with the biopsy needle 1610 of Kumar, one would have, at most, a needle 1610 with a vacuum port. One would not have the subject matter of Claim 13, because a vacuum port does not teach or suggest needle segments providing a continuous vacuum lumen.

The Examiner is respectfully requested to withdraw the rejection or provide:

1. The motivation in the prior art for combining the trocar vacuum port of Frederick with the biopsy needle of Kumar; and
2. How one would combine the vacuum port of Frederick to obtain proximal and distal needle segments which provide a continuous vacuum lumen.

Claim 14 recites, the subject matter of Claim 13 with the additional feature that the needle comprises at least one passage extending from the vacuum lumen to an outer surface of the needle. It is respectfully urged the rejection of this claim is improper for at least the following reason.

First, this rejection is improper for all the reasons set forth above with respect to claim 13.

Second, even if one combined the two references together, the combination would not teach or suggest a passage extending from a vacuum lumen to an outer surface of the needle.

The Examiner's rejection does not appear to address the subject matter of Claim 14.

Withdrawal of the rejections is requested.

Claims 16-18:

Claims 16-18 are rejected as obvious over Kumar in view of Frederick and Miller (6,638,235).

This rejection is improper for all the reasons set forth above with respect to the Examiner's application of Kumar and Frederick in combination with Kumar.

In addition, the Examiner's application of Miller '824 is also improper. The Examiner states Miller '824 discloses

"The distal needle segment of the Miller et al. device includes a tissue receiving port (43) and is made of an alloy which may consist of a non-metallic material."

The element 43 of Miller is not a tissue receiving port. Miller '824 teaches at column 8, lines 9-11:

“Thus, the motor 20 includes a vaned motor 42 that is mounted on a hollow *tubular axle* 43 extending through the motor housing 39.” Italics added.

**It is respectfully urged that the Examiner may not apply an axle of Miller as being a tissue receiving port.** This rejection ignores the plain language of Miller, and is contrary to Miller’s own teaching.

The rejection of Claims 16-18 should be withdrawn.

**Miller’s teaching of Proximal vs Distal:**

As noted previously, the Examiner’s rejections of the pending claims relies on an incorrect reference to proximal portions of Miller as “distal”, and distal portions of Miller as “proximal.” As noted in previous responses, the Examiner’s rejection includes the following reasoning:

The device comprises a *distal* needle segment 50 as shown in Figure 3A. The *distal* needle segment has a lateral tissue receiving port 55 and is *distal* from the target site when the device is in operation. (italics added).

The Examiner’s most recent final rejection also seems to say that the Examiner is free to pick what is proximal and what is distal.

This construction of “proximal” and “distal” by the Examiner is contrary to the teachings of Miller. Miller ‘824 at column 21, claim 1, Claim 1 recites:

....an inner cannula slidably disposed within said outer lumen and defining a inner lumen from an open *distal end* to an open *opposite proximal end*, said inner cannula defining a cutting edge at said *open distal end* operable to sever tissue projecting through said tissue receiving opening;....” (italics added)

Miller at column 22, claim 7 also recites:

“..a collection trap removably mountable to said handpiece and in communication with said *proximal end* of said inner lumen.” (italics added)

So, not only does Miller’s own text show the Examiner has misconstrued element 55 of Miller as a lateral tissue receiving port, but this text from Miller also indicates the directions “proximal” and “distal” as used in Miller are opposite to the Examiner’s interpretation.

**Miller’s teaching regarding materials:**

As explained previously, the Examiner’s rejection is contrary to the express teachings of Miller regarding materials. Miller’824 explains at column 8, lines 29-34...:

“In fact, with the exception of outer cannula 15, trocar tip 16 and inner cannula 17, every component of the biopsy apparatus in accordance with the present invention can be formed of a non-metallic material....” (underlining added)

Accordingly, the portions of Miller cited by the Examiner do not support the rejection previously, or in the most recent rejection. Instead, Miller teaches away from proximal and distal needle segments formed of different materials.

New claims. It is respectfully urged that new Claims 21-23 further distinguish over the art of record, and the Examiner is requested to consider allow all pending claims.

Based on the foregoing, all pending claims are in a condition for allowance. Accordingly, Applicant respectfully requests reconsideration and an early notice of allowance.

Respectfully submitted,

/Gerry Gressel/  
Gerry Gressel, reg #34,342  
Johnson & Johnson

10/808,078  
END5293USNP

One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(513) 337-3535

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